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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,521	05/18/2005	Michael R. Emmert-Buck	4239-73127-03	7250

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EXAMINER	
CALAMITA, HEATHER	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,521	EMMERT-BUCK ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *8 and 15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-7 and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/2005; 4/3/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the following species: the additional method step of claim 7, the manipulation of assaying of a biomolecule and a nucleic acid in the reply filed on January 24, 2007 is acknowledged. The traversal is on the ground(s) that the claims have a special technical feature of an External Movement inhibitor device and searching the different species would not be burdensome on the Office. This is not found persuasive because Englert disclose the features of claim 1 where the External Movement inhibitor device is given it broadest reasonable interpretation as Applicants do not specifically define this term in the specification. Additionally, with respect to burden, searching the different species would place a burden on the office as each additional method step in combination with the generic claim requires an additional search and consideration of the art. The requirement is still deemed proper and is therefore made ***FINAL***.

Status of Application, Amendments, and/or Claims

2. Claims 1-24 are pending. Claims 8 and 15-24 are withdrawn as being directed to non-elected subject matter. Claims 1-7 and 9-14 are under examination.

Claim Interpretation

3. The term "External Movement Inhibitor device" is not defined in the specification, therefore it is broadly interpreted as anything preventing movement of the molecular species on the array. Additionally, the term "array" is not defined in the specification, therefore it is broadly interpreted as a support containing probes. A Northern blot under this interpretation meets the limitation of microarray.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rutanen et al. (Fertility and Sterility, 2000).

With regard to claim 1, Rutanen et al. teach a method for analyzing the transcriptome of a cellular sample comprising:

analyzing two or more molecular species present in a 2-dimensional array of said cellular sample, wherein said method comprises treating said 2-dimensional array with an External Movement Inhibitor device having multiple discrete partitions, so as to sequester molecules present in said array into one or more discrete regions, wherein said treatment preserves the positional relationship of the molecules of said 2-dimensional array, and permits a determination of the location(s) in said cellular sample in which said molecular species are present (see p. 1021 col. 2 under *Northern Blot*, where RNA meets the limitation of transcriptome and a northern blot is a 2D array. The bond keeping the RNA on the membrane serves as an external movement inhibitor because the bond prevents the movement of the RNA on the array (nylon membrane). The bond additionally keeps the RNA in one or more discrete regions on the membrane and permits determination of the location of the cDNA probes (molecular species) on the array.

With regard to claim 2, Rutanen et al. teach wherein said cellular sample is a cellular sample obtained from a mammal (see p. 1021 col. 1 under *Tissue Samples* where the cellular sample is a biopsy of endometrial tissue from women).

With regard to claim 3, Rutanen et al. teach the mammal is a human (see p. 1021 col. 1 under *Tissue Samples* where the cellular sample is a biopsy of endometrial tissue from women).

With regard to claim 4, Rutanen et al. teach the cellular sample is a tissue sample (see p. 1021 col. 1 under *Tissue Samples* where the cellular sample is a biopsy of endometrial tissue from women).

With regard to claim 5, Rutanen et al. teach the tissue sample is a biopsy (see p. 1021 col. 1 under *Tissue Samples* where the cellular sample is a biopsy of endometrial tissue from women).

With regard to claim 6, Rutanen et al. teach the molecular species are nucleic acid molecules (see p. 1021 col. 2 under *Northern Blot*, where cDNA is the molecular species).

With regard to claim 7, Rutanen et al. teach the method additionally comprises incubating the sequestered nucleic acid molecules of two or more regions under conditions sufficient to permit the manipulation of one or more preselected nucleic acid molecules if present at said regions, while preserving the positional relationship of said molecules relative to other molecules of said 2-dimensional array (see p. 1022 Figure 1 and legend, where the RNA is in 3 discrete regions, PAI-1, tPA and 28S and manipulated with the binding of cDNA probes. The three distinct bands indicate the positional relationship of the molecules is preserved relative to other molecules on the array).

With regard to claim 9, Rutanen et al. teach one or more of the preselected nucleic acid molecules are daiagnostic of a disease state (see the abstract and p. 1022 col. 2 under *Discussion* where menorrhagia is the disease state).

With regard to claim 10, Rutanen et al. teach the manipulation is assaying a biomolecule (see p. 1021 col. 2 under *Northern Blot* where probing the RNA on the array is assaying a biomolecule)

With regard to claim 11, Rutanen et al. teach incubating the sequestered nucleic acid molecules of all of the regions under conditions sufficient to permit the manipulation of said one or more preselected nucleic acid molecules (see p. 1021 col. 2 under *Northern Blot* where probing the RNA on the array is

manipulation of the nucleic acid molecules. Additionally as hybridization of the probes to the RNA occurs the conditions are sufficient for the manipulation).

With regard to claim 12, Rutanen et al. teach the one or more preselected nucleic acid molecules are diagnostic of a disease state (see the abstract and p. 1022 col. 2 under *Discussion* where menorrhagia is the disease state).

With regard to claim 13, Rutanen et al. teach the manipulation is assaying a biomolecule (see p. 1021 col. 2 under *Northern Blot* where probing the RNA on the array is assaying a biomolecule.

With regard to claim 14, Rutanen et al. teach the cellular sample is an extract of a cell and the 2D array is a gel or membrane that arrays the nucleic acid molecules (see p. 1021 col. 1 under *Tissue Samples* where the cellular extract is RNA extracted from the tissues samples of the women and see p. 1021 col. 2 under *Northern Blot*, where the RNA is arrayed on a nylon membrane).

Summary

5. No claims were allowable.

Correspondence

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Heather Calamita
Art Unit 1637

3/30/2007